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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,703	10/17/2002	Roger Abraham Bunce	(225/40185) Case 37497	2746

7590 05/18/2006

Trexler Bushnell Giangiorgi  
Blackstone & Marr  
105 West Adams Street  
Chicago, IL 60603

EXAMINER
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ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/089,703

Applicant(s)

BUNCE ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8 and 10-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-6, 8, 10-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 4-5, 8, 10-20 and 23-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/24060, EP 0596867 or Yang et al. (USP 5354692).

WO 96/24060 teaches in the last paragraph on page 7 through page 9 slow release agents, separate layers, hydrophobicity, semipermeable membranes and porous elements as barriers. With respect to the new limitations of flow barrier being "non-wetting" and the barrier release means being an "agent capable of wetting", the Office maintains WO 96/24060 fully teaches these limitations in reference to the slow release agents that influence the hydrophobicity of the membrane.

EP 0596867 teaches in column 7 a blocking means(16) positioned between a first zone(14) and a fluid zone(15). The second zone(17) contains a solid phase receptor that binds to reagent(16) of the first zone. Figure 1 shows the first and second zones in partial fluid contact. With respect to the new limitations of flow barrier being "non-wetting" and the barrier release means being an "agent capable of wetting", the Office maintains EP 0596867 fully teaches these limitations in reference to the slow release agents that influence the hydrophobicity of the membrane.

Claims 1-2, 4-5, 8 and 10-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 930317.

WO 930317 on page 4 teaches a bidirectional flow device. Page 7 lines 16+ teach a first segment for receiving a sample, a second region at which analyte capture

reagents are immobilized, an absorbent reservoir, a supply of liquid reagent and a soluble barrier. Page 11 in the first full paragraph through page 15 teaches a reversible flow technique that has been read on the claimed "liquid flows over the analyte capture region at least twice". With respect to the new limitations of flow barrier being "non-wetting" and the barrier release means being an "agent capable of wetting", the Office maintains WO 930317 fully teaches these limitations in reference to the slow release agents that influence the hydrophobicity of the membrane.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/24060, EP 0596867, WO 930317, Yang et al. or Deutsch et al. in view of Skjak-Braek et al. (USP 5,459,054).

See over WO 96/24060, EP 0596867 and WO 930317 supra.

These references are silent to the specifically claimed release means, such as the claimed glucopyranoside (OBDG hereafter).

Skjak-Braek et al. teach in column 7 example the use of OBDG with a semipermeable membrane as a dialyzable surfactant that will change its surface properties based upon the amount of dialysis. OBDG is advantageous in a test device because it can alter the permeability based upon the amount of fluid flowing through the device (e.g. dialyzing).

It would have been within the skill of the art to modify WO 96/24060, EP 0596867, WO 930317, Yang et al. or Deutsch et al. in view of Skjak-Braek et al. and use OBDG to gain the above advantages.

### ***Response to Arguments***

Applicant's arguments filed 3/6/06 have been fully considered but they are not persuasive.

Applicants' state WO 96/24060 fails to teach a barrier means which prevents flow. These remarks are not commensurate in scope with the instant claims. The claims never define a barrier that prevents flow. Applicants' further state WO 96/24060 does not teaches a barrier release means. The Office maintains WO 96/24060 teaches slow release materials which have been read on the claimed barrier release means.

Applicants' state EP 0596867 teach PVA as a barrier means which is fluid permeable and cannot be read on the impermeable barrier of the invention. These remarks are not commensurate in scope with the instant claims. The claims never define a barrier that prevents flow. Applicants' state EP 0596867 does not teach impregnating the surfactant into the porous medium. Only pending claim 8 contains this language, so these remarks are not commensurate in scope with claims 1-2, 4-5, 10-20 and 23-24 and no further comment is necessary. With respect to claim 8, it would have been inherent if the taught surfactant were added to the porous medium that this medium would meet the claimed requirements of "impregnated".

Applicants' state WO 930317 manipulates flow by the use of soluble barriers and does not teach the claimed separate barrier release means. The claims do not exclude

the barrier release means as being the fluid flow of the sample and the Office maintains this rejection is proper.

Applicants' state the 35 USC 103 rejection of claim 6 is not proper because claim 1 from which claim 6 depends defines over the art of record. For the reasons above, the Office maintains all of the claims have been properly rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander  
Primary Examiner  
Art Unit 1743